

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>ICR0001</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/JP2004/001614</b>	International filing date (day/month/year) <b>16.02.2004</b>	Priority date (day/month/year)	
International Patent Classification (IPC) or national classification and IPC <b>C07K14/79, C07K7/06, C07K7/08, C07K1/26, C07K1/34, C07K1/22, C12P21/06, A61K38/40, A61K38/08, A61K38/10, A61P37/00</b>			
Applicant <b>KOMINE, Kenichi</b>			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/JP2004/001614

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 

This report is based on translations from the original language into the following \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
 
  - international search (Rule 12.3 and 23.1(b))
  - publication of the international application (Rule 12.4)
  - international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
 

the international application as originally filed/furnished

the description:
 

pages 1-7 \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:
 

nos. \_\_\_\_\_ as originally filed/furnished

nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos.\* 1-3, 5-15 \_\_\_\_\_ received by this Authority on 02.02.2005

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:
 

sheets 1/4-4/4 \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3.  The amendments have resulted in the cancellation of:
 

the description, pages \_\_\_\_\_

the claims, nos. 4 \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 

the description, pages \_\_\_\_\_

the claims, nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/JP2004/001614Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims	2, 5-11, 13-15	YES
	Claims	1, 3, 12	NO
Inventive step (IS)	Claims	2, 5-11, 13	YES
	Claims	1, 3, 12, 14-15	NO
Industrial applicability (IA)	Claims	1-3, 5-15	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Document 1: Rochard, E. et al., FEBS Lett, 1989, Vol. 255, No. 1, pages 201 to 204

Document 2: Bourne, Y. et al., J. Mol. Biol., 1992, Vol. 227, No. 3, pages 938 to 941

Document 3: Hutchens, T.W. et al., Proc. Natl. Acad. Sci. USA, 1991, Vol. 88, No. 8, pages 2994 to 2998

Document 4: Mead, P.E. et al., Nucleic Acids Res. 1990, Vol. 18, No. 23, page 7167

The inventions set forth in claims 1, 3 and 12 lack novelty and do not involve an inventive step in the light of documents 1 and 2. Documents 1 and 2 set forth a polypeptide containing a Phe-Lys-Asp amino acid sequence with a molecular weight of less than 25kDa, obtained by fragmenting human lactoferrin with a protease.

The invention set forth in claim 12 lacks novelty and does not involve an inventive step in the light of documents 3 and 4. Documents 3 and 4 indicate that human or bovine lactoferrin is fragmented with protease then refined, and a polypeptide containing a Phe-Lys-Asp amino acid sequence is isolated and refined.

The invention set forth in claims 14 and 15 does not

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

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**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

involve an inventive step in the light of documents 1 to 4. It would be easy for a person skilled in the art to determine the amino acid sequence of part of the polypeptide set forth in documents 1 to 4, and to produce a synthetic peptide from said amino acid sequence.

The inventions set forth in claims 2, 5 to 11 and 13 are not disclosed in documents 1 to 4, and are therefore novel and involve an inventive step. Documents 1 to 4 do not indicate that a polypeptide containing a Phe-Lys-Asp amino acid sequence with a molecular weight of less than 25kDa is obtained by fragmenting lactoferrin with elastase, or that said polypeptide has inflammation-inducing activity, and it would not be easy for a person skilled in the art to conceive of these features in the light of documents 1 to 4.